Audit Diagnostics

ZINC
Hitachi User Defined Reagent

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Standard	Storage
AD063	2 X 40 ml	ZINC	1 X 1 ml	15 - 25°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Zinc in serum, plasma and urine on Hitachi® automated analysers.

SUMMARY AND EXPLANATION[2]:

Zinc is the second most abundant trace element in humans. It is an integral part of more than two hundred enzymes. Nutritional zinc deficiency is fairly prevalent and symptoms include retardation growth and skeletal maturation, testicular atrophy and hepatosplenomegaly.

Decreased levels are found in patients with hepatic cirrhosis gastrointestinal disease, intestinal bypass and Crohns disease. Decreased levels have also been found in patients with renal disease due to protenuria

PRINCIPLE OF THE TEST:

Zinc forms with 2-(5-Brom-2-pyridylazo)-5-(N-propyl-N-sulfopropylamino)-phenol a red chelate complex. The increase of absorbance can be measured and is proportional to the concentration of total zinc.

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read and follow instructions for use. Deviations from the described procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Orange liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

This assay is designed to run on Hitachi® clinical chemistry analysers. Refer to the relevant users manual or laboratory internal practice for routine maintenance procedures. See enclosed application sheet.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	Bicarbonate Buffer pH 9.8	200 mmol/l
	Sodium Citrate	170 mmol/l
	Dimethylglyoxime	4 mmol/l
	5-Br-PAPS	50 µmol/l
	DETERGENTS	

REAGENT PREPARATION AND STABILITY:

Component is ready for use.
Before use, mix reagent by gently inverting the bottle.
If stored and handled properly, components are stable until expiry date stated on label.

TYPE OF SPECIMEN: [2]

Use serum, heparin plasma or urine specimen. Specimen must be completely cleared before assay.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.
General Chemistry Calibrator	AD983	Hitachi® Analyser	N/A
General Chemistry Control Level 1	AD922	Hitachi® Consumables	N/A
General Chemistry Control Level 2	AD932	General Laboratory Equipment	N/A

Calibration:
Using the recommended calibrator with values determined for Zinc, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Control results are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.

At intervals established by the Laboratory QC Programme

CALCULATION:

The analyser automatically calculates the Zinc activity in the sample.

(Converstion Factor: Qty in µmol/L = Qty in µg/dl x 0.153).

EXPECTED VALUES: [1]

	µg/dl	µmol/l
Men	72.6 – 127	11.1 – 19.5
Women	70 – 114	10.7 – 17.5
Urine	300 – 800	µg/24 h

Each laboratory should establish its own expected values. The Zinc results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear up to 400µg/dl (61.2 µmol/l).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:
Results of study are as follows:

Bilirubin (mixed isomers):	Less than 10% interference up to 600 µmol/l Bilirubin.
Haemolysis:	Less than 10% interference up to 2.5 g/l Haemoglobin.
Lipemia:	Interference at 1.25 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.8 µmol/L

Precision:

Within Run N = 20	Mean (g/l)	SD	% CV	Between Run N = 20	Mean (g/l)	SD	% CV
Level 1	15.9	0.197	1.24	Level 1	22.5	0.241	1.07
Level 2	30.8	0.307	1.00	Level 2	43.3	0.358	0.83

BIBLIOGRAPHY:

1. Johnsen and R. Eliasson. Evaluation of a coercially available kit for the colorimetric determination of zinc. International Journal of Andrology. 1987, 10.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54.

SYMBOLS:

The following symbols are used in the labelling of Audit Diagnostics systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer		
CE	CE Mark - Device complies with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

Manufactured By: AUDIT DIAGNOSTICS, Business & Technology Park, Carrigtwohill, Co. Cork (Ireland)
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Revision No 00 Issued on 23rd Aug 2010

Zinc Hitachi® Instruments Settings
Catalogue No: AD063

Audit Diagnostics

HITACHI 717®: (Temperature: 37°C)

CHEMISTRY PARAMETERS	
TEST CODE	**[ZN]**
ASSAY CODE	[1 Point] - [10] – [ ]
SAMPLE VOLUME (SERUM)	[15] - [0] - [0]
SAMPLE VOLUME (URINE)	[1] - [0] - [0]
R1 VOLUME	[300] - [0] - [00383] – [28]
R2 VOLUME	[0] - [0] - [00383] – [0]
WAVELENGTH	[800] - [570]
CALIB. METHOD	[Linear] -[2] -[2] –[0] – [_]
STD (1) CONC. POS.	[0.0] - [18]
STD (2) CONC. POS.	[30.0] - [20]
STD (3) CONC. POS.	[0] - [10]
STD (4) CONC. POS.	[0] - [10]
STD (5) CONC. POS.	[0] - [10]
STD (6) CONC. POS.	[0] - [10]
SD LIMIT	[0.1]
DUPLICATE LIMIT	[220]
SENSITIVITY LIMIT	[2000]
ABS LIMIT (INC/DEC)	[-32000] - [32000]
PROZONE LIMIT	[0] - [0] - [Lower]
EXPECTED VALUE	[0] - [100]
PANIC VALUES	[__] - [__]
INSTRUMENT FACTOR	[Y=aX+b] a[1.0] b[0]

[__] User Defined

HITACHI 911/912®: (Temperature: 37°C)

CHEMISTRY PARAMETERS		
TEST CODE		**[ZN]**
ASSAY CODE		[1 POINT] - [10]
WAVELENGTH (SUB-MAIN)		[800] - [570]
ASSAY POINT		[30] - [0]
DILUTION		[__] - [__]
SAMPLE VOLUME (µL)		[15] - [__]
ABS LIMIT		[0] - [INCREASE]
PROZONE LIMIT		[0] - [LOWER]
REAGENT (µL)	R1	[300] - [0] - [0]
	R2	[0] - [0] - [0]
	R3	[0] - [0] - [0]
	R4	[0] - [0] - [0]
CALIBRATION TYPE		[LINEAR] - [2] - [2]
SD LIMIT		[999]
DUPLICATE LIMIT		[3200]
SENSITIVITY LIMIT		[2000]
SI ABS. LIMIT		[-32000] - [32000]
UNIT		[__] - [__]
INSTRUMENT A		[1.00]
FACTOR (Y=AX+B) B		[0] - [0]
STD 1		[__] - [__]
STD 2		[__] - [__]
STD 3		[0] - [0]
STD 4		[0] - [0]
STD 5		[0] - [0]
STD 6		[0] - [0]

[__] User Defined.

HITACHI 902®: (Temperature: 37°C)

CHEMISTRY PARAMETERS		
TEST NAME		**[ZN]**
ASSAY CODE		[1 POINT] - [10] - [__]
ASSAY POINTS		[30] - [0] - [0] - [0]
WAVELENGTH (SUB-MAIN)		[800] - [570]
SAMPLE VOLUME (µL)		[15]
REAGENT (VOL-POS-BOTTLE SIZE)	R1	[300] - [__] - [__]
	R2	[0] - [__] - [__]
	R3	[0] - [__] - [__]
CALIBRATION		[LINEAR] - [2] - [2]
CALIB 1 (CONC/POS)		[__] - [__]
CALIB 2 (CONC/POS)		[__] - [__]
CALIB 3 (CONC/POS)		[__] - [__]
CALIB 4 (CONC/POS)		[__] - [__]
CALIB 5 (CONC/POS)		[__] - [__]
CALIB 6 (CONC/POS)		[__] - [__]
S1 ABS		[__]
K FACTOR		[__]
K 2 FACTOR		[10000]
K 3 FACTOR		[10000]
K 4 FACTOR		[10000]
K 5 FACTOR		[10000]
A FACTOR		[0]
B FACTOR		[0]
C FACTOR		[0]
SD LIMIT		[999]
DUPLICATE LIMIT		[3200]
SENSITIVITY LIMIT		[2000]
S1 ABS. LIMIT (LOW/HIGH)		[-32000] - [32000]
ABS LIMIT		[0] - [INCREASE]
PROZONE LIMIT		[32000] - [UPPER]
PROZONE (END POINT)		[35]
EXPECTED VALUES		[__] - [__]
INST FACTOR (A - B)		[1] - [0]
KEY SETTING		.....

[__] User Defined.

HITACHI 704®: (Temperature: 37°C)

CHEMISTRY PARAMETERS	
TEST CODE	**[ZN]**
ASSAY CODE	[1 (1POINT)] - [32] - [0]
SAMPLE VOLUME(µL)	[15]
R1 VOLUME	[300] - [__] - [NO]
R2 VOLUME	[0] - [__] - [NO]
WAVELENGTH	[800] - [570]
CALIB. METHOD	[LINEAR]
STD (1) CONC. POS.	[__] - [__]
STD (2) CONC. POS.	[__] - [__]
STD (3) CONC. POS.	[0] - [0]
STD (4) CONC. POS.	[0] - [0]
STD (5) CONC. POS.	[0] - [0]
STD (6) CONC. POS.	[0] - [0]
UNITS	[__]
SD LIMIT	[999]
DUPLICATE LIMIT	[3200]
SENSITIVITY LIMIT	[0]
ABS LIMIT (INC/DEC)	[0] - [INCREASE]
PROZONE LIMIT	[0] - [LOWER]
EXPECTED VALUE	[__] - [__]
INSTRUMENT FACTOR	[1.00]

[__] User Defined.

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